PREPARING QUALITY AND TECHNICAL IMPLEMENTING PROCEDURES

Quality Implementing Procedure ID: YMP-LBNL-QIP-5.2, Rev. 4, Mod. 2 *Effective: 07/11/03*

1. PURPOSE

This Quality Implementing Procedure (QIP) describes the initiation, content, preparation, review, approval, distribution, changes to, and rescission of the Yucca Mountain Project (YMP) Lawrence Berkeley National Laboratory (LBNL) QIPs and Technical Implementing Procedures (TIPs).

2. SCOPE

This QIP applies to the activities of the Preparer, Technical Reviewer(s), Engineering Assurance (EA) Manager, Bechtel SAIC Company, LLC (BSC) Quality Assurance (QA) Representative, Principal Investigator (PI) or designee, and the Project Manager (PM), during QIP and TIP generation and review. The YMP-LBNL-QIPs and TIPs are controlled documents that are written to implement the requirements of the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P.

The QIPs describe specific requirements for conducting and documenting quality-affecting activities in support of site-characterization (e.g., site recommendation, license application, and performance confirmation) tasks. QIPs shall describe interfaces with applicable upper-tier DOE/OCRWM Administrative Procedures (APs) and DOE/OCRWM Line Procedures (LPs), when appropriate. The contents, review, and control requirements for the QIPs shall also be governed by this procedure, YMP-LBNL-QIP-6.1, *Document Review*, and AP-6.1Q, *Document Control.*

The TIPs describe technical and scientific tasks that are repetitive and standardized. The contents, review, and control requirements for the TIPs shall be governed by this procedure, YMP-LBNL-QIP-6.1 and AP-6.1Q. The PI determines whether a TIP or use of the scientific notebook is appropriate. One-time-only or preliminary experimental tasks are documented in the scientific notebooks as part of the scientific processes/methods developed in accordance with AP-SIII.1Q, *Scientific Notebooks.*

3. PROCEDURE

3.1 Initiating Preparation of a QIP or TIP

3.1.1 Any **staff member** working on the YMP may propose the development of a QIP to the EA Manager or designee, or of a TIP to an appropriate PI or designee.

3.1.2 For proposed QIPs, the **EA Manager** or designee shall:

A. decide if a formal procedure is warranted;

B. decide if a OCRWM AP, or other program level procedure should be directly followed, or if a QIP should be developed;

C. explain the resolution to the requester; and

D. refer unresolved issues to the PM for final resolution.

3.1.3 For proposed TIPs, the **PI** or designee shall:

A. decide if a formal procedure is warranted;

B. explain the resolution to the requester; and

C. refer unresolved issues to the PM for final resolution.

Documenting the actions of Section 3.1 is only required for a new QIP (or TIP) if the requester or EA Manager (or PI) deem it necessary. However, the rationale for developing a procedure shall be documented in Section 2, "Scope," of the procedure.

3.2 Content and Preparation of QIPs and TIPs

3.2.1 For QIPs, the **EA Manager**, or designee shall assign a unique identifying number (e.g., YMP-LBNL-QIP-QARD section #). The EA Manager, or designee shall determine the level of detail and oversee the preparation and distribution of all QIPs.

3.2.2 For TIPs, the **EA Manager** or designee, with input from the appropriate PI, shall assign a unique identifying number (e.g., YMP-LBNL-TIP/Task Acronym-1.0). The appropriate **PI** or designee shall determine the level of detail and oversee the preparation and distribution of each TIP.

3.2.3 QIPs and TIPs shall be organized into ten Sections with headings as identified below. Headings that are not applicable shall be designated in the procedure as such (e.g., "None," "Not applicable"). These ten sections are:

1. **PURPOSE** — a summary statement of the procedure objective;

2. **SCOPE —** a description of the general circumstances, organization(s) and personnel to which the procedure applies;

3. **PROCEDURE** — a step-by-step description of the work process, including prerequisites, limits, safety considerations, process parameters, technical and/or regulatory requirements, and environmental conditions. Notes shall not be used in procedures.

This section also includes, as appropriate, identification of quality verification and hold points, methods for ensuring that the work is performed as required, and associated activities and methods for altering the sequence of required activities.

Applicable elements of calibration and equipment operations information contained in Vendor or Manufacturer's Technical Manuals shall be incorporated or attached to TIPs. Any changes or updates to the information contained in Vendor Technical Manuals provided by the equipment suppliers that affects the calibration and associated equipment operations shall be included in a revision to the TIP, as applicable, in accordance with AP-12.1Q, *Control of Measuring and Test Equipment and Calibration Standards.* All other manuals, or procedures contained in manuals may be included by reference as long as they are:

- uniquely referenced (by document number, revision, etc.),
- available at the work place,
- readily available to all potential users, and
- reviewed and submitted to YMP Records Processing Center (RPC);

4. **RECORDS —** a list of QA record packages or individual QA records, identified as QA Records, a list of non-QA records packages or individual records identified as Non-QA Inclusionary Records, and/or individual records identified as Non-QA Exclusionary Records;

5. **RESPONSIBILITIES —** specific statements defining critical positions, organizations and organizational interfaces responsible or necessary for the effective implementation of the procedure;

6. **ACRONYMS AND DEFINITIONS —** a location for identifying relevant acronyms and clarifying or defining terms, to help the reader understand the content of the procedure;

7. **REFERENCES** — a list of documents, including procedures, referenced in the procedure's text;

8. **ATTACHMENTS** — a list of supplementary information, forms, figures or other materials not included in the required sections of the QIP/TIP;

9. **REVISION HISTORY —** a summary of the changes made to the procedure since the original version was issued, including the reasons for the changes; and

10. **APPROVALS** — a signature page, identifying the Preparer, and confirming the acceptable review of the procedure by the proper technical, EA, BSC QA Representative, PI and PM reviewers, as applicable.

Each page of the procedure shall show the unique procedure identifying number, revision and modification number.

3.3 Review and Approval of QIPs and TIPs

3.3.1 During the development process, the **Preparer** shall deliver copies of initial and revised QIP and TIP drafts, supporting documents, and related materials to the PI (if a PI designee is the preparer) and EA Manager for his/her information. The Preparer shall uniquely identify each draft (e.g., Draft 00A, Draft 00B, etc.) and final revision and modification (e.g., Rev. 0, Mod. 0; Rev. 0, Mod. 1 etc.)

During the development and review process, the **Preparer** shall retain the originals of the initial draft, all subsequent formally reviewed drafts, associated review forms (i.e., Review Record, Comment Sheet. Attachments 2 and 4, respectively in YMP-LBNL-QIP-6.1), applicable review criteria, and the final document. Upon approval of the document, the **Preparer** shall transfer the procedure and associated reviews to the YMP-LBNL Records Coordinator for processing in accordance with AP-6.1Q, and AP-17.1Q, *Record Source Responsibilities for Inclusionary Records*.

3.3.2 All new and revised QIPs and TIPs shall undergo at least two technical reviews and one EA review by qualified individuals, selected by the Deputy PM. For QIPs, the EA Manager and the Preparer shall provide reviewer recommendations. For TIPs, the PI shall recommend the technical reviewers, and in consultation with the EA Manager shall recommend the EA reviewer. The BSC QA Representative shall also review both QIPs and TIPs. All identified reviewer(s) shall review the draft QIPs or TIPs according to YMP-LBNL-QIP-6.1.

If an organization other than YMP-LBNL will perform work under a proposed QIP or TIP or revision thereof, then an appropriate person(s) representing that organization shall review the procedure according to AP-5.1Q, *Plan and Procedure Preparation, Review, and Approval*.

3.3.3 The **Preparer** shall complete the comment resolution, incorporate the reviewers' comments and submit the final draft QIP or TIP to the **EA Manager** (for QIPs) and the **PI** (for TIPs) to determine when the document should be effective and shall assign the effective date to the document.

3.3.4 The QIP or TIP will be submitted to the **PM** for final review/approval. Any comments, other than editorial, resulting from the **PM**'s review/approval shall be documented according to YMP-LBNL-QIP-6.1.

3.3.5 The **Preparer** shall incorporate the PM's comments (if any) into a final version of the QIP or TIP, add the effective date to the document header and then route the original copy to all reviewers for their approval signatures. Each responsible individual shall sign and date, in dark ink, in the appropriate signature space. The final signature shall be that of the PM. The document is then ready for controlled distribution.

3.4 QARD Requirements Matrix

3.4.1 For QIPs only, the **EA Manager** or designee shall develop a new or updated QARD requirements matrix (QRM) for each new revision or modification of the procedure, and submit it to the BSC QA Representative for review according to YMP-LBNL-QIP-6.1. The **BSC QA Representative** shall review the QRM for accuracy, record any comments on review form(s), return the draft QRM and forms to the EA Manager or designee for comment resolution.

3.4.2 The EA Manager or designee shall submit any identified exceptions to the QARD requirements to the **Requirements Matrix Coordinator** in accordance with AP-2.19Q, *Quality Assurance Requirements and Description Requirements Matrix and Impact Evaluation*. The **Requirements Matrix Coordinator** shall submit the QRM, including justification documentation for exceptions, to the Office of Quality Assurance (OQA) for review, in accordance with AP-2.19Q.

3.4.3 Upon comment resolution, the **EA Manager** or designee shall notify the Requirements Matrix Coordinator, in writing, that the review is completed and shall identify the needed changes. The submitted input shall identify:

A. where each applicable QARD requirement is addressed;

B. where requirements are inapplicable, with justification for each inapplicability; and

C. where exceptions to requirements have been taken, with justification for each exception.

3.4.4 Upon a QARD revision, the Requirements Matrix Coordinator notifies the **EA Manager** or designee, in writing, of the need to perform a QARD revision impact evaluation, in accordance with AP-2.19Q. The **EA Manager** shall evaluate whether changes to the QIPs are necessary, and shall initiate the change process, as appropriate.

3.5 Distributing a QIP or TIP

3.5.1 The **Records Coordinator** or designee shall update the QIP or TIP active controlled document list, the Table of Contents, and provide for controlled distribution of QIPs and TIPs to the workplace in accordance with requirements in AP-6.1.

3.5.2 The **controlled document recipient(s)** shall make the document readily available at the workplace, use only the latest revision with all approved changes, and destroy or mark a superseded document accordingly.

3.5.3 The **Records Coordinator** shall handle copies of superseded versions of such documents in a controlled manner, in accordance with AP-6.1Q.

3.6 Making Changes to an Active QIP or TIP

If, while implementing a QIP or TIP, work cannot be accomplished as described without producing an undesirable result, the **staff members** performing the work (or the responsible PI) shall stop work. The staff members, with supervisory input, shall determine what kind of changes shall be made to the QIP or TIP prior to resuming work.

Three types of changes can be made to QIPs and TIPs: editorial changes, modifications, and revisions. In addition to these types of changes, expedited changes can be made to TIPs.

3.6.1 Editorial Changes shall be processed as Modifications (see 3.6.2) and are limited to the following:

- grammatical or spelling corrections,
- renumbering sections that do not affect the chronological

sequence of the work.
- changing the title or number of the document
- updating organizational title(s), when responsibilities remain the same

3.6.2 Modifications

Modifications are changes to a QIP or TIP that are minor or affect only one section of the document. Modifications shall be implemented by the EA Manager or designee for QIPs, and the PI or designee for TIPs as follows:

A. preparing draft pages for the document, including sidebars to indicate the location of the change.

B. obtaining reviews of the YMP-LBNL QIP/TIP in accordance YMP-LBNL-QIP-6.1 as follows :

- the TIP by two technical reviewers, the EA Manager or designee, BSC QA Representative and the PI or designee (if the PI is not the originator); and

- the QIP by two technical reviewers, the EA Manager or designee, and BSC QA Representative;

C. making the appropriate changes to the Revision History section of the procedure, including the reasons for the changes;

D. updating the "modification number" on all pages, in a sequential pattern (e.g., beginning with “0", "1”, etc.).

E. obtaining approval signatures on the new approval section of the modified YMP-LBNL QIP/TIP; the **PM** shall approve all modifications to QIPs and TIPs;

F. issuing the modifications to controlled document recipients, with instructions according to AP-6.1Q.

The **Preparer** shall assure that record packages consisting of the original signed YMP-LBNL QIP/TIP, review documentation and other supporting materials are created and submitted to the YMP-LBNL Records Coordinator for submittal to YMP RPC in accordance with AP-17.1Q.

3.6.3 Revisions

Revisions to active QIPs and TIPs are required following issuance of a third modification to the document, or sooner if the changes to the document are substantial. They are made by:

A. reviewing the historical changes to the (a) QIP by the EA Manager, and (b) TIP by the PI;

B. assigning a Preparer, who would renumber all QIP or TIP pages to indicate the new revision and modification numbers. The revision number shall be one greater than the previous revision number, and the modification number shall be reset to zero. The "Revision History" section of the new revision to the document shall also be updated, including:

- identification of changes,
- the reason(s) for the change(s);

C. completing of requirements in Sections 3.1, 3.2, 3.3; and

D. submitting of an updated input to the requirements matrix database, as appropriate, by the EA Manager (see Section 3.4).

3.6.4 Expedited Change(s) to a TIP

If the responsible **PI** or designee determines that a modification (Section 3.6.2) or a revision (Section 3.6.3) to a TIP would cause an unreasonable delay in proceeding with the task, then an expedited change to the procedure (including documentation of deviation from the approved technical process) can be made. Such changes are subject to review, usually after the task has proceeded, and thus work performed under TIPs with expedited changes is done at risk of future invalidation.

The **Preparer** shall make expedited changes to a TIP by:

A. attaching a memo with a description of the change(s) and justification, and making corresponding handwritten text change(s), to the local copy of the TIP, and/or cross referencing the changes in the scientific notebook;

B. dating and initialing the handwritten change(s); and

C. processing the change per this procedure as a modification, revision, or rescission, as soon as practical but within 90 working

days. If the expedited change is found to be unacceptable, then any work performed under that expedited change is subject to technical review in which an evaluation shall be performed for acceptability under the appropriate PI's authority. The **Preparer** shall create a record package containing a copy of the expedited change and the resolution of the resulting review and submit it to the Records Coordinator for submittal to the YMP RPC.

3.7 Rescinding a QIP or TIP

3.7.1 Rescinding a QIP

Any **staff member** may suggest the rescission of a QIP to the EA Manager. The **EA Manager** or designee shall evaluate the suggestion and confer with the PM and all affected organizations. If all parties are in agreement and with BSC QA Representative concurrence and PM approval, the EA Manager shall rescind the procedure, justify the action in a memo to the procedure records package. Unresolved issues involving the BSC QA Representative shall be referred to successively higher levels of management within YMP-LBNL and BSC QA for resolution. The **Records Coordinator** or designee shall assure that the YMP list of controlled documents is updated accordingly and shall notify all controlled document holders to return, destroy or mark their copies of the rescinded document, according to AP-6.1Q. Upon rescission of a QIP, the EA Manager shall notify the Requirements Matrix Coordinator to update the QARD requirements matrix in accordance with section 3.4, as appropriate.

3.7.2 Rescinding a TIP

Any **staff member** may suggest the rescission of a TIP to the appropriate PI. The **PI** or designee shall evaluate the suggestion and confer with the EA Manager and all affected organizations. If all parties are in agreement and with BSC QA Representative concurrence and PM approval, the PI shall rescind the procedure, and justify the action in a memo to the procedure records package (with a copy to the EA Manager.) Unresolved issues involving the BSC QA Representative shall be referred to successively higher levels of management within YMP-LBNL and BSC QA for resolution. The **Records Coordinator** shall assure that the YMP-LBNL list of controlled documents is updated accordingly and shall notify all controlled document holders to return, destroy or mark their copies of the rescinded document, according to AP-6.1Q.

4. RECORDS

4.1 QA Records

QIPs and TIPs associated with this procedure shall be submitted to the YMP-LBNL Records Coordinator for issuance as controlled documents, and submittal with associated reviews to the YMP RPC, in accordance with AP-17.1Q.

QA records associated with this procedure may be submitted as a records package or as individual records to consist of the final approved QIPs/TIPs, expedited changes, revisions, modification records, supporting reviews (e.g., Review Record/Comment Sheet, QARD reviews, outside reviews documented by memo, electronic mail, or AP-5.1Q review forms).

4.2 Non-QA Inclusionary Records

Reviewed drafts

4.3 Non-QA Exclusionary Records

General procedure distribution memoranda (if used)

5. RESPONSIBILITIES

5.1 The **Project Manager** (PM) is responsible for oversight of the review process for QIPs and TIPs, and for the final approval of all new and revised QIPs and TIPs. The PM is also responsible for final approval of the rescission of the QIPs and TIPs.

5.2 The **Deputy PM** is responsible for assignment of technical reviewers for the QIPs, TIPs, and revisions thereof.

5.3 The **Principal Investigator (PI)** is responsible for the preparation (or delegation thereof), review, distribution, implementation and rescission of applicable TIPs. The PI is responsible for related training of personnel to the TIPs.

5.3 The **EA Manager** is responsible for assigning procedure numbers to QIPs and TIPs, and overseeing and coordinating preparation, review, revision, distribution and rescission of QIPs/TIPs, and preparing the QARD requirements matrix for QIPs. The EA Manager or designee is also responsible for the review and approval of QIPs/TIPs.

5. 4 The **BSC QA Representative** is responsible for reviewing and concurring with all QIPs, TIPs, QARD requirements matrices, and modifications thereto. The BSC QA Representative is also responsible for concurring to the rescission of these documents.

5.5 **Staff Members** are responsible for suggesting the development of new QIPs, TIPs and modifications thereto. The staff members involved in the preparation or review of procedures are responsible for following this procedure, YMP-LBNL-QIP-6.1, and turning over related documentation to the YMP-LBNL Records Coordinator for submittal to YMP RPC in accordance with AP-17.1Q.

5.6 The Records Coordinator or designee is responsible for obtaining document identifiers from the EA Manager, providing the controlled distribution of QIPs and TIPs, (and revisions / modifications thereof) in accordance with AP-6.1Q, and for submitting all records to the RPC, as appropriate.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

AP	OCRWM Administrative Procedure
BSC	Bechtel SAIC Company, LLC
DI	Document Identifier
DOE	U. S. Department of Energy
EA	Engineering Assurance
LBNL	Earnest Orlando Lawrence Berkeley National Laboratory
LP	OCRWM Line Procedure
OQA	Office of Quality Assurance
OCRWM	Office of Civilian Radioactive Waste Management
PI	Principal Investigator
PM	Project Manager
QA	Quality Assurance
QARD	Quality Assurance Requirements and Description
QIP	YMP-LBNL Quality Implementing Procedure
QRM	QARD Requirements Matrix
RPC	YMP Records Processing Center
TIP	YMP-LBNL Technical Implementing Procedure
YMP	Yucca Mountain Project

6.2 Definitions

QARD Requirements Matrix (QRM): A system by which QARD requirements are mapped and tracked against procedures implementing the requirements, including the specific YMP-LBNL-QIPs.

Quality Implementing Procedure: Each QIP describes an aspect of the YMP-LBNL implementation of YMP QARD requirements or project level procedure.

Staff Member: Any scientist, engineer, research or technical associate, technician, or student research assistant performing quality-affecting work for YMP-LBNL.

Technical Implementing Procedure: Each TIP describes YMP-LBNL technical and/or scientific tasks that are repetitive and standardized.

7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description (QARD)*
AP-2.19Q, *Quality Assurance Requirements and Description Requirements Matrix and Impact Evaluation.*
AP-5.1Q, *Plan and Procedure Preparation, Review, and Approval*
AP-6.1Q, *Document Control*
AP-17.1Q, *Record Source Responsibilities for Inclusionary Records*
AP-SIII.1Q, *Scientific Notebooks*
AP-12.1Q, *Control of Measuring and Test Equipment and Calibration Standards*
YMP-LBNL-QIP-6.1, *Document Review*

8. ATTACHMENTS

None

9. REVISION HISTORY

10/21/96 — Revision 0, Modification 0:
YMP-LBNL-QIP-5.2 issued, to supersede and replace YMP-LBNL-QIP-5.0 and YMP-LBNL-QIP-5.1.

06/02/97 — Revision 1, Modification 0:
Revised procedure to introduce the term engineering assurance and to re-define position responsibilities.

02/03/99 — Revision 2, Modification 0:
Revised procedure to introduce requirements for the Planning Document initiation, content, review, approval, revision, modification and rescission. A number of format and editorial changes made. All procedure pages are affected. No impact to on-going activities.

09/17/99 — Revision 3, Modification 0:

Deleted requirements for the Master Planning Document (MPD) and replaced it with requirements for the Development Plan (DP) to be consistent with AP-2.13Q. Also included references to AP-2.14Q, AP-2.15Q, AP-6.1Q, AP-SIII.1Q and YAP-12.3Q. Deleted MPD/QIP/TIP Modification Record.

09/22/00 — Revision 4, Modification 0:

Deleted requirements for the Development Plan (DP) and references to cancelled procedures AP-2.13Q, AP-2.14Q, AP-2.15Q and YMP-LBNL-QIP-6.0. Updated the QARD Requirements section to reference AP-2.19Q.

03/15/02 — Revision 4, Modification 1:
Updated procedure to include new position of YMP-LBNL Deputy Project Manager for assignment of technical reviewers, updated OQA Representative to BSC QA Representative, added reference to OCRWM LPs, updated YAP-12.3Q to AP-12.1Q, and other minor modifications.

07/11/03 — Revision 4, Modification 2:
Updated procedure to include reference to the OQA review of the QRM and any associated justifications per the QARD Rev 13. Other minor format modifications.

10. APPROVALS

(Signature on File)

Preparer: Vivi Fissekidou — Date

(Signature on File)

Technical Reviewer: Ivelina McClung — Date

(Signature on File)

Technical Reviewer: Peter Persoff — Date

(Signature on File)

EA Reviewer: Nancy Aden-Gleason — Date

(Signature on File)

BSC QA Concurrence: Stephen Harris — Date

(Signature on File)

Project Manager: Gudmundur Bodvarsson — Date